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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
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EXAMINER
LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)
10/029,137	NGYUYEN MAI
Examiner	**Art Unit**
Gerald G Leffers Jr.	1636

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/2/03* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-54* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other

DETAILED ACTION

Receipt is acknowledged of a response to the written description requirement made in Paper No. 7, mailed 11/19/02. In the response, filed 4/02/03 as Paper No. 9, several arguments were made concerning the rejoinder of different groups. In particular, several arguments were made concerning the impropriety of restricting between distinct inventions in a single, broad generic claim. These arguments are addressed by the following restriction requirement as well as by comments that follow.

Upon further review of the claims and the restriction made in Paper No. 7, and in view applicant's arguments, it is evident that a new restriction requirement is required. It is the examiner's position that the original restriction made in Paper No. 7 was done according to linking claim practice, where the linked group, and broadly recited invention, will be considered if the broadly recited linking claim is found to be allowable. However, the previous examiner did not explicitly include language to that effect. Also, it is apparent that the subject matter of some of the groups can be further restricted. For these reasons, a new restriction requirement follows.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7 and 11, drawn to an isolated nucleic acid, a vector and host cell comprising the isolated nucleic acid, classified in class 536, subclass 23.1; class 435, subclass 320.1.

II. Claims 8-10, drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, or conservative substitutions thereof, classified in class 530, subclass 351.

III. Claims 12-14, drawn to an antibody, classified in class 530, subclass 387.1.

IV. Claims 15-24, and 27-28, drawn to a nucleic acid-based method of screening for screening for a test agent that modulates tissue angiogenesis or tumorogenesis in a cell, classified in class 435, subclasses 6, 29.

V. Claims 15-19 and 25-28, drawn to a protein detection-based method of screening for a test agent that modulates tissue angiogenesis or tumorogenesis in a cell, classified in class 435, subclasses 4, 7.1, 29.

VI. Claims 15-19 and 27-28, drawn to a method of screening a test agent that modulates tissue angiogenesis or tumorogenesis wherein the biological activity of the EG-1 gene product is assayed in a cell, classified in class 435, subclass 4.

VII. Claims 29-36 and 39-42, drawn to a method of prescreening for an agent comprising contacting an EG-1 nucleic acid with a test agent and detecting the specific binding of the test agent to the EG-1 nucleic acid, classified in class 435, subclass 6.

VIII. Claims 29-34 and 37-42, drawn to a method of prescreening for an agent comprising contacting an EG-1 protein with a test agent and detecting the specific binding of the test agent to the EG-1 polypeptide, classified in class 435, subclass 7.1.

IX. Claims 43-47, drawn to a transgenic animal comprising a recombinantly modified EG-1 gene that does not encode a functional EG-1 protein, classified in class 800, subclass 8.

X. Claim 48, drawn to a nucleic acid-based assay for determining a predilection to developing one or more symptoms of a disease characterized by abnormal angiogenesis by determining overexpression of the EG-1 gene product in a biological sample, classified in class 435, subclass 6.

XI. Claim 48, drawn to a protein-based assay for determining a predilection to developing one or more symptoms of a disease characterized by abnormal angiogenesis by determining overexpression of the EG-1 gene product in a biological sample, classified in class 435, subclass 7.1.

XII. Claims 49-50, drawn to a method of inhibiting angiogenesis comprising inhibiting the expression EG-1 gene product (e.g. targeting EG-1 gene expression using anti-sense, etc.), classified in class 514, subclasses 44.

XIII. Claims 49-54, drawn to a method of inhibiting angiogenesis by interfering directly with the activity of an EG-1 gene product (e.g. administration of an EG-1 protein, EG-1 specific antibody, etc.), classified in class 514, subclass 2.

Claim 15 link(s) inventions of Groups IV-VI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the

allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 29 link(s) inventions of Groups VII-VIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 29. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 48 link(s) inventions of Groups X-XI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 48. Upon the

allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 49 link(s) inventions of Groups XII-XIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 49. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because:

Inventions of Groups I-III and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the instant inventions are not disclosed as usable together have different physical and chemical structures, different physical properties and biological functions: polynucleotide (Group I), polypeptide (Group II), antibody (Group III) and transgenic animal (Group IX). Thus, the different compositions have different functions and effects. Therefore, the inventions of these different groups are capable of supporting separate patents.

Inventions I and IV, VII, X & XII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group I can be used in the methods of Groups IV, VII, X or XII. Alternatively, the nucleic acids can simply be used for expression of the EG-1 polypeptide.

Inventions of Group I and Groups V, VI, VIII, XI, XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as usable together and have

different modes of operation, different functions and different effects. For example, the isolated nucleic acids of Group I are not required for any of the methods of the other groups.

Inventions of Group II and Groups IV, V, VI, VII, X, XI, & XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as usable together and have different modes of operation, different functions and different effects. For example, the isolated polypeptides of Group II are not required for any of the methods of the other groups.

Inventions of Group II and Groups VIII & XIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated polypeptides of Group II can be used in the methods of Group VIII or in the methods of Group XIII. Alternatively, the isolated proteins can be used to generate an antibody against the EG-1 gene product.

Inventions of Group III and Groups IV, VI-VIII, X & XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as usable together and have different modes of operation, different functions and different effects. For example, the antibodies of Group III are not required for practicing the methods of Groups IV, VI-VIII, X and XII.

Inventions of Group III and Groups V, XI & XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the EG-1 specific antibodies of Group III can be used in the different methods of Groups V, XI and XIII.

Inventions of Groups IV-VIII, X-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of Groups IV-VIII, X-XIII are biologically and functionally different and distinct from one another and thus do not render the inventions of the other groups obvious. The methods of Groups IV-VIII, X-XIII comprise steps that are not required for or necessarily present in the methods of the other groups: exposing a cell to a test agent and determining its effect on EG-1 transcription (Group IV), exposing a cell to a test agent and determining its effect on EG-1 protein levels in a cell (Group V), exposing a cell to a test agent and determining its effect on the biological activity of the protein (Group VI), a DNA binding assay (Group VII), a protein binding assay (Group VIII), detection of overexpression of a nucleic acid in a biological sample from an individual (Group X), detection of an over-abundance of an EG-1 protein in a biological sample from an individual (Group XI), administration of a nucleic acid to an individual in order to inhibit abnormal angiogenesis (Group XII), and administration of a peptide, antibody or small drug to an individual in order to inhibit abnormal angiogenesis (Group XIII). The end result of the different methods of Groups IV-VIII, X-XIII are different:

identification of a test agent that affects the level of expression of EG-1 nucleic acids in a cell (Group IV), identification of a test agent that affects the level of EG-1 protein in a cell (Group V), identification of a test agent that affects the biological activity of an EG-1 protein in a cell (Group VI), identification of a test agent that can bind an EG-1 nucleic acid (Group VII), identification of a test agent that can bind an EG-1 protein (Group VIII), detection of an overexpressed EG-1 nucleic acid in a biological sample (X), detection of an over-abundance of an EG-1 protein in a biological sample (XI), inhibition of the expression of an EG-1 nucleic acid in a subject in need thereof (XII), and inhibition of EG-1 protein activity in a subject in need thereof (XIII). Thus, the operation, function and effects of these different methods are different and distinct from one another. Therefore, the inventions of these different groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because the non-patent literature search required for examination of the different groups is different (e.g. DNA-binding assays versus PCR amplification of a nucleic acid in a biological sample; using an antibody to detect overexpression of a protein in a sample versus using an antibody to inhibit protein function in a subject), restriction for examination purposes as indicated is proper.

Response to Arguments

The inclusion of the linking claim language in the current restriction should address applicant's concern that the most broadly recited claims in each group will not be examined. With regard to the assertion that a search for prior art pertinent to the nucleic acid is expected to

identify any prior art (if such exists) pertinent to the polypeptide encoded by the polynucleotide sequence, this is not necessarily true. There are databases that are based solely on protein sequence and which would not be searched by inputting a nucleic acid sequence. Moreover, a search of the art that is not strictly sequence-based is also required. With regard to there not being a search burden in searching both Groups I and II together, all that need be shown in order to demonstrate a search burden is that the products of the different groups have a different classification, as is the case here.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.
Examiner
Art Unit 1636

Ggl
June 17, 2003